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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,855	03/19/2008	Marc V. Gorenstein	524287-0353594(WAA-348-PC	2017
43840 7590 12/27/2010 Waters Technologies Corporation 34 MAPLE STREET - LG MILFORD, MA 01757				
EXAMINER				
HARWARD, SOREN T				
ART UNIT		PAPER NUMBER		
1631				
MAIL DATE		DELIVERY MODE		
12/27/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,855

Applicant(s)

GORENSTEIN ET AL.

Examiner

Soren Harward

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2,5-9,11,14-18,20 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,10,12,13,19,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Unless otherwise stated, "the previous Office action" refers to the non-final rejection mailed 14 Jun 2010.

Amendments Received

1. Amendments to the specification and claims were received and entered on 26 Oct 2010.

Status of the Claims

2. Withdrawn: 2, 5–9, 11, 14–18, 20, 23–27
3. Examined herein: 1, 3, 4, 10, 12, 13, 19, 21, 22

Withdrawn Objections

4. The objections to the specification are hereby withdrawn in view of Applicant's amendments to the same.

Withdrawn Rejections

5. The rejection of claims 10, 12 and 13 under 35 USC § 112, first paragraph, is hereby withdrawn in view of Applicant's amendments.
6. The rejection of claims 10, 12 and 13 under 35 USC § 101 is hereby withdrawn in view of Applicant's amendments.

Maintained Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3, 4, 10, 12, 13, 19, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Even though the rejection itself is being maintained from the previous Office action, the rationale for the rejection is new.
10. Claims 1 and 10 recite the limitation "said portion including the subsets and entities of the first injection and the second injection other than those in said subsets" which is self-contradictory. The portion cannot "include the subsets ... of the first [and the second] injection" and simultaneously exclude "said subsets". Hereinafter, the limitation will be interpreted as though it recited "said portion including the entities in the first and second injections that are neither members of the subset of entities from the first injection, nor members of the subset of entities from the second injection". The Examiner further suggests that the claim be clarified by having the first step recite "choosing a first subset of entities from a first injection", with analogous changes in the second step, and using the designators "first subset" and "second subset" as appropriate in the other steps of the claim, thus removing possible ambiguity as to which subsets Applicant is referring in the subsequent claim elements.
11. As noted in the previous Office action, claim 19 recites the limitation "assigning reference retention times based on the retention time map", which does not specify to what the reference retention times are assigned. Are they assigned to peaks, to entities, to subsets of entities, to injections, or something else? Hereinafter, this limitation will be interpreted as

though the reference retention times are assigned to entities, to be consistent with claims 1 and 10.

12. None of the dependent claims remedy the deficiencies in their respective independent claims, so they are likewise rejected.

Response to Arguments - Rejections Under 35 USC § 112, Second Paragraph

13. In the reply filed 26 Oct 2010, Applicant argues that the claims as amended are no longer indefinite (pp. 9–10). While Applicant's amendment does address most of the issues noted in the previous Office action — with the exception of the "assigning reference retention times" in claim 19, as noted above — the amendment also introduces new limitations that are not particularly pointed out, also as explained above. Hence, the rejection is maintained, albeit largely for different reasons; the changes were necessitated by Applicant's amendments.

Maintained Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claims 1, 3 and 4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

16. The rationale that follows has been updated to conform to current Office practice regarding examination of process claims under 35 USC § 101.

17. According to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that weigh against the eligibility of a process include insufficient recitation of a machine or transformation and lack of application of a law of nature.

18. None of the steps of claim 1 are explicitly or inherently tied to a particular machine, such as a programmed computer or an LC/MS system. The preamble of the claim states that the method is "computer implemented", but does not specify how the computer is involved in the performance of the method; the involvement may be entirely tangential, such as providing a list of entities in one of the injections from which the subset is chosen, and leaving the remaining steps to be performed by hand. Second, the preamble indicates that the data being analyzed are LC/MS data, but the data themselves are not inherently tied to an LC/MS machine. Thus, the claim is not sufficiently tied to a particular machine.

19. The method does not encompass any step that transforms a particular article into another state or thing, such as a step of analyzing a sample injected into an LC/MS system. The recited steps merely transform data.

20. The method of claim 1 "track[s] entities in an LC/MS system" by identifying related entities in different LC/MS datasets. This "tracking" and identification is merely a subjective determination — albeit a scientifically-informed one — of which data points correspond to one another. Thus, the claim is not directed to an application of a law of nature.

21. Claim 1 thus fails to meet the standard for statutory eligibility. Since neither claim 3 nor claim 4 remedies this deficiency, they are likewise rejected.

Response to Arguments - Rejections Under 35 USC § 101

22. In the reply filed 26 Oct 2010, Applicant argues that stating in the preamble that the method is "computer-implemented" is sufficient to render the method statutory (pp. 10–11). As explained above, this statement alone is insufficient to tie the method to a particular machine. Even though Applicant correctly notes that failing to meet the "machine or transformation test" does not automatically render a method non-statutory (p. 11), this factor does still weigh against

statutory eligibility. As explained above, claim 1 meets multiple factors that weigh against its statutory eligibility and none that weigh in favor of its eligibility, hence the arguments are unpersuasive and the rejection is maintained.

Maintained Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

24. Claims 1, 3, 4, 10, 12, 13, 19, 21 and 22 are rejected under 35 USC § 102(b) and 35 USC 102(e) as being anticipated by Higgs (US 5,885,841; cited by Applicant on IDS of 11 Jun 2008).

25. The rationale that follows has been expanded slightly to address the newly-added claim limitations, but is substantially similar to that presented in the previous Office action.

26. With respect to claim 1, Higgs teaches a method of comparing two samples of proteins (*i.e.*, “entities”), comprising the following:

- a. fractionating two protein digest samples (clm 37(a–d)), possibly by liquid chromatography (clms 42 and 43); samples of organic species in general are claimed in clms 52–55

- b. matching peak pairs between the two sets of samples (clm 37h); the process of matching constitutes both the "comparing the entities" and "identifying entities" steps, and the matched peaks constitute the "subset of entities from a first injection" and the "subset of entities from a second injection"
 - c. identifying retention time intervals for the peaks (clm 44), which constitutes "constructing a retention time map"
 - d. aligning the retention times of the samples (clm 46), which constitutes "assigning reference retention times" to the peaks
 - e. identifying peaks in either of the injections that do not correspond to a peak in the other injection, and assigning retention times to those unmatched peaks (23:11–12, 22–23, 31–24)
 - f. outputting results of the peak matching (clm 37(i)) or the unmatched peaks (19:44–52), which constitutes "tracking entities"
27. With respect to claims 10 and 19, Higgs teaches an apparatus that implements this method (clms 14–22). Higgs further teaches that the peaks are matched based on the chromatographic profile of the peaks (23:12–15), the profile being defined by the chromatographic signal (*e.g.* Fig. 4 and 5, and descriptions at 9:57–67 and 10:62–11:9), thus constituting choosing the peaks "based on intensity", as recited in claim 19.
28. With respect to claims 3, 12 and 21, Higgs teaches arrangements of data along defined axes (Fig. 3); since an axis is inherently sorted, this constitutes sorting the matched data.
29. With respect to claims 4, 13 and 22, Higgs teaches aligning the retention times of the two samples (clm 45), which inherently requires (or results in) determining whether one entity has a corresponding entry in the retention time map of the other sample. The alignment to a standard further establishes a "defined value" for the retention time if two entities match, and

Higgs teaches the optional use of dynamic time warping to align two samples (clm 47), which constitutes interpolating the retention time values if they don't match.

30. Higgs thus anticipates the claimed inventions.

Response to Arguments - Claim Rejections Under 35 USC § 102

31. In the reply filed 26 Oct 2010, Applicant argues that

Higgs, neither in the claims nor elsewhere in the reference, discloses or fairly suggests constructing a retention time map based on matching entities of the subsets and assigning, based on the retention time map, reference retention times to the subsets and entities from the first and second injections other than those of the subsets, as set forth in Claim 1.

(p. 14). As explained above, Higgs teaches identifying retention time intervals for the peaks, which constitutes "constructing a retention time map", and then assigning those retention times to unmatched peaks; *i.e.* the peaks that are members neither of the subset chosen from the first injection nor of the subset chosen from the second injection. Higgs thus teaches the disputed limitation.

32. Applicant further argues that Higgs does not teach choosing subsets of entities based on intensity (p. 15). However, as explained above, Higgs teaches matching peaks (*i.e.* selecting the subsets) based on chromatographic profiles, and the chromatographic profiles are defined by intensities. This, Higgs also teaches this contested limitation.

33. The arguments are therefore unpersuasive, so the rejection is maintained.

Conclusion

34. No claim is allowable.

35. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Soren Harward whose telephone number is (571)270-1324. The examiner can normally be reached on Mon-Thu 9:00-18:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Soren Harward/
Examiner, Art Unit 1631

/Lori A. Clow, PhD/
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